



**APPLICATION FOR REGISTRATION
CHARITABLE PHARMACY DRUG OUTLET**

(Expires March 31 Annually)

APPLICATION REQUIREMENTS:

- ☐ **\$105.00 application or owner/location change fee** All fees are nonrefundable.
- ☐ **A description of the organization, drug donation and dispensing process.** The description (Policies & Procedures) must address all items including drug acquisition of donated drugs, storage, security, dispensing of donated drugs, disposal of unusable drugs, record keeping and staff training.
- ☐ **If you answer “YES” to any disciplinary action questions,** including pending disciplinary actions, all notices, citations, etc. and fully executed Board orders must be provided along with a detailed explanation.
- ☐ **Legible 8.5” x 11” floor plan,** which identifies the location of drug storage, sinks, refrigerators, windows and doors. Windows and doors must be marked as secured or unsecured.

***Priority processing will be given to complete applications.** All applications submitted to the Board that are not complete and processed within 6 months from applicant signature will be expired. Once expired, applicants who wish to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees.

Mail completed application and all required documentation to:

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland OR 97232

Questions? Contact us:

Telephone: (971) 673-0001
www.oregon.gov/pharmacy
pharmacy.licensing@bop.oregon.gov

The purpose of the program is to provide a process to make donated prescription drugs available to needy or uninsured individuals and those with limited access to pharmaceuticals. Under the rules in this Division, a Charitable Pharmacy that is registered with the Oregon Board of Pharmacy (Board) may accept drugs for donation and distribution within this state when the pharmacist can reasonably be assured of the purity and integrity of the drug. The program may not include categories of drugs specified by the Board as excluded from the program.

Listed below are the required supplemental items needed to complete your application.

1. Oregon Administrative Rules for Charitable Pharmacies can be found in [Chapter 855, Division 044](#).
2. We will process your registration when we have received all required paperwork and fee(s).
3. Charitable pharmacies that are co-located with an existing registered pharmacy may name a pharmacist employed by the existing pharmacy as its pharmacist. Charitable pharmacies that are not co-located with an existing registered pharmacy and does not have a pharmacist on staff must employ a Consultant Pharmacist.
4. Application must include a description of the organization and dispensing process (referred to as policies & procedures or P&P [Have specific items numbered]). The P&Ps must be created, maintained and enforced in accordance with current regulations and shall address the following, at a minimum: drug acquisition of donated drugs, storage, security, distribution of donated drugs, disposal of unusable drugs, record keeping and staff training
 1. Drug Acquisition of donated drugs –
 - How and from where are the drugs obtained?
 - Who verifies the purity and integrity of the donated drugs?

2. Drug Storage –
 - Where are drugs stored?
 - How is proper drug storage maintained?
3. Drug Security –
 - Who has access?
4. Donated Drug Dispensing, including preparation, labeling and delivery -
 - Describe prescription filling, labeling and dispensing processes
 - Detail all items included on prescription label
 - Who performs the drug utilization review and final verification of all drugs dispensed?
5. Drug Disposal of unusable drugs –
 - Who is responsible to quarantine and dispose of outdated, adulterated, or otherwise unusable drugs?
 - Which staff are permitted to perform these duties?
6. Personnel -
 - Staff Training
 - o Initial and ongoing
 - Accountability/Responsibility
 - o Describe each personnel's responsibilities
 - Drug Access
7. Record Keeping/Documentation -
 - Where and how are all related records to the above P&Ps stored?
8. Other

This information must be submitted with your application for approval. An application will include items 1- 7 (8 if applicable) and must be submitted as an attachment with each item clearly identified. An application is not complete until all items have been received and are compliant with Oregon laws and Rules.

Please note the following: Upon Board issuance of a registration, registrant agrees that all information provided as part of the application, including policy and procedures, may not be altered without written Board approval and any deviation may be considered unprofessional conduct and grounds for discipline.

5. ***NEW OR RELOCATED PHARMACIES must submit a legible 8.5" x 11" floor plan***, drawn to scale (can be hand drawn). Floor plans must identify the location of drug storage, sinks, refrigerators, windows and doors. Additionally, **you must note** whether windows/doors are secured or unsecured.
6. Each company or location address, even if under common ownership, must submit a separate application for registration.
7. You must pay a registration fee for each application for **a New Registration, an Ownership Change or a Location Change**. The Board can only accept payment by check or money order. **All fees are nonrefundable.**

Examples of a required ownership change application include but are not limited to: corporate restructure; LLC to a Corporation, Corporation to LLC; acquisition of assets; or additions or deletions of an owner. An ownership change requires submission of a copy of the sales agreement or other documentation that verifies proof of new ownership.

If you are completing these forms to report a **Name Change** only, you do not pay a fee.

8. Oregon law **requires** each facility to conduct an annual report by **February 1st** annually. The annual report form is available on the Board's website. This form needs to be completed and available for inspection by the Board at all times.
9. **Oregon Revised Statutes and Administrative Rules** are accessible on our web site at: https://www.oregon.gov/pharmacy/pages/laws_rules.aspx#OREGON_LAWS_&_RULES. You may purchase a set for \$25 (check the box on the application if you wish to purchase one or more sets).

Please be aware that your application will be scheduled for review once all required paperwork and fee(s) are received. Your registration is to be in your possession PRIOR to dispensing drug products in Oregon.

Charitable Pharmacy Drug Outlets expire March 31 annually and fees are not prorated. Renewals are due and must be post-marked by February 28 annually, which is one (1) month prior to the expiration date of your license. Renewal notices will be mailed out mid-January.

APPLICATION FOR REGISTRATION

CHARITABLE PHARMACY

(Expires March 31 Annually)
Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland OR 97232
pharmacy.licensing@bop.oregon.gov



FOR BOARD USE ONLY	[0339] \$ 105.00 [0326] \$ 25.00
RECEIPT #	_____
CHECK #	_____
ENTERED BY	_____
PERSON ID #	_____
APPLICANT ID #	_____

Please check all that apply:

- ☐ Charitable Pharmacy
- ☐ Laws & Rules per set, please indicate quantity _____

Fee: \$ 105.00

Fee: \$ 25.00

TOTAL ENCLOSED: _____
ALL FEES ARE NONREFUNDABLE

Type of Application – Check all that apply:

- ☐ **New Facility Application - Start / Effective Date:** _____
- ☐ **Change of Ownership or Location Change – Effective Date of Change:** _____
A change of ownership or location **requires** the submission of a new application and registration fee **within 15 days**.
Registration Number: _____
- ☐ **Legal documentation of the change in ownership or control, for example, a stock purchase agreement and/or and executed contract for sale, etc.**
- ☐ **Registration Reinstatement (Registration has been lapsed for a period of one year or more)**
Registration Number: _____
- ☐ **Name Change Only (No fee required)**
Registration Number: _____

Please PRINT or TYPE

WARNING: ORS 689.405(1) The furnishing of false information is grounds to deny registration.

Trade or Business Name (DBA): _____

Full Legal / Owner Name: _____

Federal Tax ID # or Owner SSN: _____

Physical Location Address: _____

City: _____ State: _____ Zip: _____

Phone Number: _____ FAX #: _____

Registration & Renewal Mailing Address: _____

City, State, Zip: _____

Licensing Contact Person: _____ Title: _____ Contact Phone: _____

Licensing Contact Person E-mail Address: _____

Facility Website: _____

Hours / Days Establishment is open: _____AM to _____PM _____Through _____

Consultant Pharmacist / Pharmacist In Charge: _____ License No: _____

Point of Contact Person (If different from above: _____ Title: _____

Point of Contact Address: _____

Point of Contact City, State, Zip: _____

Point of Contact Phone Number: _____

Point of Contact Email Address: _____

Please answer all of the following:

1. Has disciplinary action been taken, or is any such action currently pending or proposed against any of the persons or establishments listed on this application, by any State or Federal Authority in connection with a violation of any federal or state drug law or regulation? If "yes", attach a detailed explanation of the incident and describe any penalty incurred. You must provide a copy of all documents pertaining to discipline. This includes Notice of Disciplinary Actions, Board Orders and other related documents.	☐ Yes ☐ No
2. Before dispensing any donated drug, a pharmacist conducts a visual inspection of each donated drug to ensure that the drug has not expired, been adulterated or misbranded and is in its original, sealed packaging, and that based on this inspection and on the accuracy of the Donor's Form, the drug is safe to distribute.	☐ Yes ☐ No
3. The charitable pharmacy does <u>NOT</u> accept any controlled substances; non-prescription drugs, drugs in a container or package that does not contain a product identification label (PIL), except that a drug in a manufacturer's original container or a manufacturer's blister pack does not need to bear a PIL; an FDA REMS (Risk Evaluation and Mitigation Strategy) drug; or a drug donated from another state.	☐ Yes ☐ No
4. Is this facility a small business? A small business is defined as a corporation, partnership, sole proprietorship or legal entity, which is independently owned and operated from all other businesses and which has 50 or fewer employees?	☐ Yes ☐ No

Ownership Information

Type of Ownership:

- ☐ Publicly Held Corporation ☐ Corporation ☐ Limited Liability Company ☐ Sole Proprietorship
- ☐ Partnership – Including Limited Liability Partnership and Limited Partnership ☐ Charitable Organization
- ☐ Government / Educational Institution

Owner Name _____

Parent Company Name (If owned by another entity) _____

Complete the information below for all owners. You must include at least one of the following: CEO, President, Owner, or Members of LLC and Registered Agent. If a corporation, include the names of the corporate officers and the names of the stockholders who own the five largest interests.

1.

Name

Title

SSN/Federal Tax ID

Address

City, State, Zip

Phone Number

Email Address

2.

Name

Title

SSN/Federal Tax ID

Address

City, State, Zip

Phone Number

Email Address

3.

Name

Title

SSN/Federal Tax ID

Address

City, State, Zip

Phone Number

Email Address

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FINAL CHECKLIST:	
1.	Appropriate Fee Included?
☐ \$105.00 application or owner/location change fee Total Fee Enclosed: _____	
2.	Required Documentation* – an application is incomplete if all requested documentation is not provided. *Priority processing will be given to complete applications. All applications submitted to the Board that are not complete and processed within 6 months from applicant signature will be expired. Once expired, applicants who wish to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees.
A.	☐ Policies & Procedures that include all of the following: 1. Drug Acquisition of Donated Drugs - Located on page # _____ 2. Drug Storage - Located on page # _____ 3. Drug Security - Located on page # _____ 4. Donated Drug Dispensing - Located on page # _____ 5. Disposal of unusable drugs - Located on page # _____ 6. Personnel - Located on page # _____ 7. Record Keeping / Documentation - Located on page # _____ 8. Other - Located on page # _____ Please clearly identify each of the 7 required sections. Not providing page numbers, which identify the required information above, will significantly increase the time it takes to review the policies and procedures.
B.	☐ If you answer "YES" to any disciplinary questions; disciplinary actions, pending disciplinary actions, and fully executed Board orders must be provided along with a detailed explanation.
C.	Legible 8.5"x11" Floor Plan of facility, drawn to scale (can be hand drawn). Floor plans must identify the location of drug storage, sinks, refrigerators, windows and doors. You must note whether windows/doors are secured or unsecured.
D.	☐ All signatures

The undersigned hereby states that all the information contained in this application for registration is complete, true and correct, that they have read and are familiar with the applicable laws and rules of the Oregon Board of Pharmacy, and that such provisions of the law will be faithfully observed.

Signature

Title (Owner, Partner, Etc.)

Date

ALL RETURNED PAYMENTS WILL BE ASSESSED A \$35.00 RETURNED PAYMENT FEE
PURSUANT TO ORS 30.701(5)